UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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IN RE PFIZER INC. SECURITIES LITIGATION

No. 04 Civ. 9866 (LTS)(JLC)
No. 05 md 1688 (LTS)

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AMENDED OPINION AND ORDER[1]

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LAURA TAYLOR SWAIN, UNITED STATES DISTRICT JUDGE

[1] This Amended Opinion and Order includes revised attorney appearances, but is otherwise identical to the Court's March 22, 2010, Opinion and Order.

The above-captioned putative class action litigation has been consolidated for pretrial purposes in the Southern District of New York pursuant to the June 21, 2005, order of the Judicial Panel on Multidistrict Litigation. The member actions share factual questions arising from allegations that Pfizer, Inc. ("Pfizer"), and other named defendants violated federal and state securities laws and committed fraud by misrepresenting and/or concealing the safety risks of Pfizer's COX-2 inhibitor drugs, Celebrex and Bextra.

Pending before this Court are Plaintiffs'[2] and Defendants'[3] motions to preclude from introduction into evidence in the above-captioned matter pursuant to Federal Rules of Evidence 702 and 104(a) the testimony of certain experts regarding the cardiovascular risk[4] associated with Celebrex and/or Bextra. Plaintiffs move to preclude the testimony of Defendants' expert Lee-Jen Wei, Ph.D. ("Dr. Wei"). Defendants move to preclude the testimony of Plaintiffs' experts David Madigan, Ph.D. ("Dr. Madigan"), Curt D. Furberg, M.D., Ph.D. ("Dr. Furberg"), Richard A. Kronmal, Ph.D. ("Dr. Kronmal"), Lawrence Baruch, M.D. ("Dr. Baruch"), Joel S. Bennett, M.D.

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2 "Plaintiffs" refers to the putative class of investors who purchased or acquired Pfizer stock between October 31, 2000 and October 19, 2005 (the "Class Period") on whose behalf Lead Plaintiff Teachers' Retirement System of Louisiana is prosecuting this action.

3 "Defendants" refers to Pfizer and corporate officers Henry McKinnell, John LaMattina, Karen Katen, Joseph Feczko, and Gail Cawkwell.

4 Although the complaint (docket entry no. 51 - see, e.g., at 18-25) speaks in terms of cardiovascular risk, as did the order (drafted jointly by the parties) setting the Daubert hearing (docket entry no. 120), Defendants sought in this motion practice to advance the argument that only evidence relating to the narrower subset of thromboembolic (i.e., clot-related) risk should be deemed relevant to the question of Defendants' potential liability in this case. While Defendants are free to argue this point as the case goes on, it is facially inconsistent with the Plaintiffs' articulation of their claims and nothing in the pleadings or in the record thus far persuades this Court that the broader question of cardiovascular risk is so irrelevant to the issues presented in this litigation as to render inadmissible evidence relating to such risk.

("Dr. Bennett"), and Nicholas P. Jewell, Ph.D. ("Dr. Jewell"). For the reasons stated below, both motions are denied.

BACKGROUND

Plaintiffs allege that Defendants violated federal and state securities laws and committed common-law fraud by concealing the results of various medical studies concerning two Pfizer drugs, Celebrex and Bextra, and by making misstatements and omissions in their public filings and statements. The surviving allegations and issues in this litigation are summarized in the Court's July 1, 2008, Opinion and Order (docket entry no. 90) concerning Defendants' motion to dismiss the Complaint, familiarity with which is presumed.

At Defendants' request and pursuant to this Court's January 12, 2009, order, a hearing was set "to determine whether, on or before December 17, 2004, there was reliable scientific evidence that Celebrex or Bextra was associated with increased cardiovascular risk (the Daubert hearing)." Following the submission of expert reports and the deposition of the experts at issue, both parties filed motions (docket entry nos. 139 and 144) to preclude expert testimony, together with voluminous exhibits. These motions were fully briefed on September 25, 2009. In late October 2009, the Court held a five-day Daubert hearing which included thorough direct and cross-examination of certain experts, the use of demonstrative exhibits, and the submission of extensive written direct testimony. Following the conclusion of the Daubert hearing, the Court ordered both parties to file supplemental submissions. These post-hearing submissions and all responses thereto were filed on January 8, 2010. The Court has listened carefully to all of the hearing testimony and has reviewed thoroughly the parties' written submissions, documentary evidence, and demonstratives. Readers' familiarity with that record is presumed. For the reasons that follow, both parties' motions to preclude expert testimony are denied.

DISCUSSION

Federal Rule of Evidence 702 provides that, "[if] scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." (West 2006). Preliminary questions of admissibility are determined by the court. Fed. R. Civ. P. 104(a). Where, as here, the admissibility of expert scientific or technical testimony is challenged, the proponent of the evidence must demonstrate admissibility to the satisfaction of the Court under Rule 104(a) by establishing scientific or technical reliability by a preponderance of the evidence. See Bourjaily v. United States, 483 U.S. 171, 175-76 (1987); Falise v. Am. Tobacco Co., 258 F. Supp. 2d 63, 66 (E.D.N.Y. 2000). The determination as to whether proffered scientific or technical evidence will "assist the trier of fact to understand the evidence or to determine a fact in issue" is in essence a question of the relevance, or "fit," of the proffered evidence. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 590 (1993). Evidence is relevant when it has "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401 (West 2006). The Court must determine whether the proffered testimony has a sufficiently "reliable foundation" to permit its consideration. Daubert, 509 U.S. at 597.

Rule 702 specifically requires examination of the qualifications of the proffered expert to testify to pertinent scientific knowledge, whether the facts or data upon which the expert

relies are sufficient, whether the methodology employed is valid and whether its application by the expert in formulating the testimony is proper. Id. at 592-93.

In Daubert, the Supreme Court held that the trial judge's "gatekeeping responsibility" requires the court to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." Id. at 589. The Daubert Court identified a number of factors that, while not constituting a "definitive checklist or test," could be considered by a district court in evaluating the reliability of a proffered expert: "whether a theory or technique had been and could be tested, whether it had been subjected to peer review, what its error rate was, and whether scientific standards existed to govern the theory or technique's application or operation." Nimely v. City of New York, 414 F. 3d 381, 396 (2d Cir. 2005) (citing Daubert, 509 U.S. at 593-94). The trial judge should "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 152 (1999). "[T]he law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." Id. at 142; see also id. at 141 ("[A]s the Court stated in Daubert, the test of reliability is 'flexible,' and Daubert's list of specific factors neither necessarily nor exclusively applies to all experts or in every case."). Questions of credibility generally do not render an expert's testimony inadmissible. See Daubert, 509 U.S. at 596; Hemmings v. Tidyman's, Inc., 285 F.3d 1174, 1188 (9th Cir. 2002). Nor should district courts prejudge the weight of conflicting evidence or substitute the judgment of the court for that of the jury. See In re Joint E. & S. Dist. Asbestos Litig., 52 F.3d 1124, 1133 (2d Cir. 1995).

Here, Defendants challenge the admissibility of testimony by six individuals trained in medicine and/or statistics proffered by Plaintiffs as evidence of increased cardiovascular risk associated with Celebrex and Bextra prior to December 17, 2004. The Court, having reviewed carefully the record, is persuaded that Plaintiffs have carried their burden of demonstrating that each of their challenged witnesses is possessed of the requisite qualifications to testify as to his respective opinion regarding the interpretation of clinical trials and/or analysis and interpretation of data.

Defendants contend, among other things, that Plaintiffs' proffered evidence that there was reliable scientific evidence prior to December 17, 2004, that Celebrex and Bextra were associated with increased cardiovascular risk is inadmissible because Plaintiffs' experts have defined cardiovascular risk too broadly and/or inconsistently, and have not presented evidence of statistically significant indicia of thromboembolic risk. As noted above (see footnote 3), this argument is inconsistent with Defendants' own articulation of the subject matter of the hearing. It bears noting that this Daubert process was initiated at an early juncture in the case, prior to significant discovery and prior to the preparation of the opinions proffered here, at Defendants' request. Defendants cannot now be heard to complain that Plaintiffs failed to tailor their opinions to a view of the issues that Defendants chose not to share until after the opinions had been formulated. Nor is the use of the term "cardiovascular" or attention to non-thromboembolic cardiovascular issues inconsistent with claims in the complaint or, indeed, with a number of statements by Defendants that are quoted in the complaint and challenged as misleading. (See, e.g., Compl. ¶¶ 41, 74-75, 84-87, 90-94, 111, 118-19, 127-29, 144, 169.) The ultimate issues for the fact finder in this litigation do not involve medical causation of injuries but, rather, include whether Pfizer should have disclosed certain information it had earlier than it did, and whether the

undisclosed information rendered misleading Defendants' public representations as to the existence of cause for concern about the safety of the two drugs.

Furthermore, Plaintiffs have demonstrated, by competent, credible testimony, that the non-thromboembolic "endpoints" utilized in their analyses of pre-December 2004 Pfizer study data are derived from scientific principles of sufficient validity and/or from Pfizer's own analytical methods. The record is sufficient to demonstrate the relevance of evidence of the associations identified in Plaintiffs' evidentiary proffers and thus to render Defendants' thromboembolic association arguments ones that go to the weight, rather than to the admissibility, of Plaintiffs' evidence.

The Court has considered carefully the record and all of Defendants' other arguments concerning the admissibility of the challenged testimony and finds that Plaintiffs have met their Rule 702 burden with respect to each of the challenged proffers. The Court's principal conclusions with respect to each of Plaintiffs' witnesses are summarized below.

The Court concludes further that Defendants have carried their Rule 702 burden with respect to the proffered rebuttal testimony of Dr. Lee-Jen Wei, principally for the reasons summarized below.

Dr. Madigan

Dr. David Madigan holds a doctorate in statistics, and is currently Professor in and Chair of the Department of Statistics at Columbia University. Dr. Madigan has taught and published extensively in the field of statistics. He has served as Director of Rutgers University's Rutgers Institute of Biostatistics and currently serves as an editor of a peer-reviewed academic statistics journal, Statistical Science. Dr. Madigan has consulted for various pharmaceutical companies and otherwise applied his scientific training to questions of drug safety and public

health. Dr. Madigan opines as to the import of a meta-analysis he performed on data that was in existence during the relevant period to determine its significance with respect to the cardiovascular safety of Celebrex. Dr. Madigan's credentials as a statistician amply qualify him to testify as an expert with respect to his interpretation of the data he analyzed. Plaintiffs have met their burden with respect to the qualifications of Dr. Madigan.

Dr. Madigan's written submissions and testimony described clearly and justified cogently his statistical methods, selection of endpoints, decisions regarding event classification, sources of data, as well as the conclusions he drew from his analysis. Indeed, Dr. Madigan's meta-analysis was based largely on data and endpoints developed by Pfizer. All four of the endpoints that Dr. Madigan used in his analysis – Hard CHD, Myocardial Thromboembolic Events, Cardiovascular Thromboembolic Events, and CV Mortality – have been employed by Pfizer in its own research and analysis. The use of Hard CHD in the relevant literature combined with the use of the other three endpoints by Pfizer in its own 2005 meta-analysis will assist the trier of fact in determining Pfizer's knowledge and understanding of the pre-December 17, 2004, cardiovascular safety profile of Celebrex. The assistance Dr. Madigan received from Dr. Lawrence Baruch, a practicing cardiologist whose qualifications are discussed infra, and Dr. Curt Furberg, a prominent cardiovascular epidemiology researcher whose qualifications are discussed infra, in the classification of deaths that occurred in the studies he reviewed was appropriate given that Dr. Madigan's own training is not in medicine. Any weaknesses in the classification of fatal adverse events made by Dr. Baruch and Dr. Furberg were attributable to the limitations of the data created by and, later in the context of litigation, produced by Pfizer. Given that the goal of Dr. Madigan's analysis was to determine what knowledge Pfizer had or could have had based on the data available to it at the time, any lack of precision in the adverse event classification consultations performed in

conjunction with Dr. Madigan's meta-analysis fail to so seriously indict Dr. Madigan's opinion as to render it inadmissible under Daubert. Nor are the differences between the fatal event classifications performed by Dr. Baruch and Dr. Furberg, and later relied upon by Dr. Madigan, so significant as to render Dr. Madigan's meta-analysis "junk science." Plaintiffs have met their burden regarding the relevancy of the content of Dr. Madigan's expert opinion to the ultimate questions of drug safety at issue in this securities litigation, as well as its satisfaction of the other Rule 702 criteria.

Dr. Furberg

Dr. Curt D. Furberg is currently Professor of Public Health Sciences and Senior Advisor to the Dean for Health Services Research and Health Policy at Wake Forest University. Dr. Furberg holds both M.D. and Ph.D. degrees and has a broad range of experience and expertise in the field of public health. He has published extensively on topics including clinical trials and non-steroidal anti-inflammatory drugs ("NSAIDs"). Dr. Furberg has been lead investigator in numerous clinical trials and worked in both the public and private sectors, having been asked by both the pharmaceutical industry and the FDA to evaluate safety of COX-2 inhibitors. Plaintiffs offer Dr. Furberg's opinions regarding the review he conducted of the medical literature and clinical studies for Celebrex and Bextra. Based on his reading of the relevant literature and review of the available study data, Dr. Furberg submits that information was available to Pfizer prior to December 17, 2004, that demonstrated a scientifically significant risk of adverse cardiovascular events associated with the use of Celebrex and Bextra.

The breadth of knowledge, experience, and expertise Dr. Furberg brings to proceedings in this case is considerable. Dr. Furberg has wide-ranging training and practice in both clinical and research settings. His opinions are based on individual study data available to Pfizer

and, to arrive at them, he employed the methods and analysis he has applied in his lengthy and distinguished career as an expert in the fields of drug safety and clinical trial design. Dr. Furberg's background in and publishing about drug safety and clinical trials well suits him to assist the jury in its determination of what, if any, association between Celebrex and/or Bextra and cardiovascular risk existed on or before December 17, 2004. Defendants' motion to preclude the testimony of Dr. Furberg is therefore denied.

Dr. Kronmal

Dr. Richard A. Kronmal is a Professor of Biostatistics and Statistics at the University of Washington and holds a doctorate in the field of biostatistics. Dr. Kronmal's academic experience involves extensive peer-reviewed publication on the topic of cardiovascular disease. He currently directs a research center at the University of Washington that designs, conducts, and analyzes clinical studies with an emphasis on cardiovascular disease. Dr. Kronmal has served on numerous data safety monitoring boards, which are responsible for ensuring the safety of patients participating in clinical trials and for monitoring such trials for possible early termination due to excessive risks. Plaintiffs offer Dr. Kronmal's opinions concerning his interpretation of Pfizer's clinical trial data, which he finds demonstrate a statistically significant cardiovascular risk associated with Celebrex and Bextra prior to December 17, 2004.

Dr. Kronmal applied his substantial specialized knowledge and experience to assess the design and results of clinical trials of Celebrex and Bextra using established statistical methods. In his analysis, he relied on SAS data provided by Pfizer, as well as on several other studies. Dr. Kronmal persuasively explained and defended, inter alia, his use of non-APTC endpoints and the particular strengths and weaknesses of certain clinical circumstances. Dr. Kronmal's qualifications

and methods satisfy the Daubert standard and his testimony derived therefrom is relevant to the determination of cardiovascular risk. Therefore, Dr. Kronmal's testimony is admissible.

Dr. Jewell

Dr. Nicholas P. Jewell is a professor of Professor of Biostatistics and Statistics at the University of California, Berkeley. Dr. Jewell's teaching and research has dealt with the design and interpretation of clinical trials. Dr. Jewell has published peer-reviewed articles in the area of the application of statistical analysis to clinical trial data, and has authored a widely used statistics-for-epidemiology textbook. Dr. Jewell is offered by Plaintiffs as a rebuttal expert, and his testimony centers on the methodologies employed in the meta-analysis performed by defense expert Dr. Lee-Jen Wei.

While he does not provide his own analysis or conclusions regarding the safety of Celebrex or Bextra prior to December 17, 2004, Dr. Jewell offers opinions relevant to the ultimate issues in this case. Dr. Jewell's report speaks directly to the weight the jury should assign to Dr. Wei's meta-analysis and his testimony will assist the jury in its interpretation and assessment of Defendants' evidence. Plaintiffs have amply sustained their burden to demonstrate the relevancy and reliability of Dr. Jewell's opinions, and thus his testimony is admissible.

Dr. Baruch

Dr. Lawrence Baruch holds an M.D. and practices cardiology as the Director of the Heart Failure and Echocardiography Programs at the Bronx Veteran Affairs Medical Center. He has also currently serves as an attending cardiologist at Mt. Sinai Hospital in New York City. Dr. Baruch is offered as a rebuttal expert by Plaintiffs. His opinions that the events witnessed in the Bextra CABG clinical trials can be generalized, that Celebrex and Bextra are associated with, contribute to, and can cause cardiovascular events, and that the available clinical data suggest that

COX-2 inhibitors increase the risk of cardiovascular events are offered to dispute the testimony offered by Defendant. Dr. Baruch's experience, including his experience training cardiology fellows and medical students, meets Plaintiffs' burden to qualify him as an expert.

Dr. Baruch's training and practice in the field of cardiology as detailed in his expert report qualify him, under Daubert, to testify regarding the cardiovascular effects of Celebrex and Bextra, especially on patients undergoing certain surgical procedures. The relationship between the two forms of Bextra, parecoxib and valdecoxib, is also properly within the scope of Dr. Baruch's expertise such that his opinions on the matter are admissible. Dr. Baruch's testimony will assist the jury in its evaluation of the weight to assign to certain clinical studies, such as the CABG trials, in determining whether Pfizer breached disclosure obligations. Defendant's motion to preclude Dr. Baruch's testimony is denied.

Dr. Bennett

Dr. Joel Bennett holds an M.D. and is a Professor of Medicine and Pharmacology at the University of Pennsylvania School of Medicine. His publications include peer-reviewed articles and textbook chapters on platelet function, and he has written specifically about NSAIDs and COX-2 inhibitors. Plaintiffs have satisfied their burden to qualify Dr. Bennett as an expert. The testimony of Dr. Bennett deals with the origin and operation of the FitzGerald (or "Imbalance") Hypothesis, Plaintiffs' posited mechanism for the harm caused by COX-2 inhibitors. This hypothesis has been deemed plausible and credible in the relevant medical literature, and is well within Dr. Bennett's field of expertise based on his training, experience, and history of publication. Dr. Bennett's testimony, while about a mechanism not proven conclusively or uniformly accepted, is far from baseless speculation and concerns a theory that has been subject to, and approved for

publication by, peer review. The testimony of Dr. Bennett satisfies the Daubert standard and Defendants' motion to preclude his testimony is denied.

Dr. Wei

Dr. Lee-Jen Wei holds a Ph.D. and is currently a Professor of Biostatistics at the Harvard University School of Public Health. He has served on the editorial boards of a number of scientific journals as well as an FDA Advisory Committee. Dr. Wei's publications in peer-reviewed journals are extensive, and he has performed numerous meta-analyses of clinical trial data in the course of his academic career. In the instant litigation, Defendants seek to offer Dr. Wei's meta-analysis of data relating to the safety of Celebrex and his interpretation thereof.[5] Defendants satisfy the standard to qualify Dr. Wei as an expert, and his opinion is clearly relevant to the ultimate issue of alleged misrepresentation or concealment of safety risk.

Dr. Wei's methodology, the validity of which Plaintiffs contest and the novelty of which Plaintiffs seek to highlight, appears to have survived the rigors of peer review at least once, and is subject to critique by virtue of its transparency. Dr. Wei's report, supplemented by his declaration, is sufficient to meet Defendants' burden of demonstrating that his testimony is the product of reliable principles and methods. He has explained his methods, which can be tested. Plaintiffs' critiques of Dr. Wei's choices regarding which trials to include in his own meta-analysis, the origins of the data he used, the date at which he undertook his meta-analysis, and at whose

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[5] The Court notes that, moments before Dr. Wei was to be cross-examined at the Daubert hearing, Defendants withdrew substantial portions of Dr. Wei's supplemental rebuttal report based on a purportedly "slight error in calculation." (Daubert Hr'g Tr. 814-15, Oct. 29, 2009.) Defendants withdrew from Dr. Wei's supplemental rebuttal report Exhibit A; Demonstrative Exhibits DE3, DE4, DE5, DE6; Exhibits 17, 18, 19, 20, 21, and 22 from Appendix D; and Tables 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, and 38. Nothing in this order should be construed to permit the admission into evidence of the withdrawn materials or the analysis on which they rely.

behest he performed his analysis all go to the weight of Dr. Wei's testimony. Given the variety of clinical trials available to aggregate and disagreement regarding which studies were of the highest medical and scientific quality, most "powerful,"[6] and appropriate to extrapolate from, Plaintiffs' main objection to Dr. Wei's methodology – his use of potentially novel "sensitivity analyses"[7] instead of patient years to account for duration when performing his meta-analysis – speaks to the appropriate weight to assign Dr. Wei's testimony, rather than its inadmissibility. Vigorous cross-examination of an expert as to a study's purported inadequacies allows the jury appropriately to weigh the alleged defects and reduces the possibility of prejudice. Fireman's Fund Fund Ins. Companies v. Alaskan Pride Partnership, 106 F.3d 1465, 1468 (9th Cir. 1997); United States v. L.E. Cooke Co., 991 F.2d 336, 342 (6th Cir. 1993). The ultimate conclusions of Dr. Wei's meta-analysis speak directly to the cardiovascular safety of Celebrex and therefore would assist a jury in its determination of Defendants' knowledge of the same. Accordingly, Plaintiffs' motion to preclude Dr. Wei's testimony is denied.

CONCLUSION

The extensive submissions that are the subject of the instant motions satisfy the standards of qualification and reliability established by Federal Rule of Evidence 702 and

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[6] The term "powerful" is used here in its statistical sense, referring to "the probability of finding a statistically significant association of a given magnitude (if it exists) in light of the sample sizes used in the study." Michael D. Green et al., Reference Guide on Epidemiology, in Reference Manual on Scientific Evidence at 362 (Federal Judicial Center 2d ed. 2000).

[7] The Court notes that Dr. Wei's "new" method was never given a precise name in the parties' filings or in the Daubert hearing testimony. The method referred to was apparently developed in 2007 and subjected to peer review soon thereafter. It was described in contrast to the method of imputation by Plaintiffs' expert Dr. Jewell, and as a "random effects model" by Defendants' rebuttal expert, Dr. William Weintraub. (Daubert Hr'g Tr. 753, Oct. 22, 2009.)

elucidated in Daubert. While the cross-motions raise significant issues with respect to potential flaws, limitations, and the credibility of the experts' opinions, these concerns go ultimately to the weight of the opinions. Because the Daubert standard is satisfied with respect to all experts whose preclusion was sought, both parties' motions are denied in their entirety.

This order resolves docket entry nos. 139 and 144.

SO ORDERED.

Dated: New York, New York
March 29, 2010

LAURA TAYLOR SWAIN
United States District Judge